Remarks

I. Support For The Amendment And Status Of The Claims

The Title has been amended to reflect the claimed subject matter. Support for the amendment of the Title is found in application no. 10/601,105 ("the present application") at page 22, line 11 *et seq.* Support for the amendment of the Title is found in priority application no. 60/101,318 ("the '318 application") at page 24, line 4 *et seq.*

Claims 21 and 23-27 have been amended, claims 22 and 28-40 have been canceled, and new claims 41-44 have been added. Claims 21, 23-27 and 41-44 are pending.

Claims 28-40 have been canceled without prejudice to or disclaimer of the subject matter therein, in order to focus prosecution on the subject matter of claims 21, 23-27 and 41-44. Applicants reserve the right to file one or more continuation applications directed to the subject matter of canceled claims 28-40.

Support for the amendment of claim 21 is found in the present application at page 22, line 11 *et seq.*; page 22, line 30; and page 38, line 6. Support for the amendment of claim 21 is found in the '318 application at page 5, line 29; page 22, lines 8-9; page 24, line 4 *et seq.*; page 24, line 28; page 26, lines 31-32; and page 40, lines 35-36.

Support for the amendment of claim 23 is found in the present application at page 22, line 21; page 25, line 16; and page 54, line 17. Support for the amendment of claim 23 is found in the '318 application at page 24, line 17; page 24 line 23; page 27, line 19, and page 58, line 32.

Support for the amendment of claim 24 is found in the present application at page 7, line 24. Support for the amendment of claim 24 is found in the '318 application at page 5, line 31.

Support for the amendment of claim 25 is found in the present application at page 26, line 1. Support for the amendment of claim 25 is found in the '318 application at page 28, line 1.

Support for the amendment of claim 26 is found in the present application at page 7, line 27; page 25, line 15; and page 54, line 17. Support for the amendment of claim 26 is found in the '318 application at page 5, line 36; page 24, line 33; and page 58, line 32.

Support for the amendment of claim 27 is found in the present application at page 24, line 20. Support for the amendment of claim 27 is found in the '318 application at page 26, line 20.

Support for claim 41 is found in the present application at page 26, line 1. Support for claim 41 is found in the '318 application at page 28, line 1.

Support for claim 42 is found in the present application at page 54, line 20. Support for claim 42 is found in the '318 application at page 58, line 36.

Support for claim 43 is found in the present application at page 8, line 3. Support for claim 43 is found in the '318 application at page 6, line 8.

Support for claim 44 is found in the present application at page 8, lines 5-6. Support for claim 44 is found in the '318 application at page 6, lines 12-13.

No new matter has been added by this amendment.

II. The Objection To The Title Should Be Withdrawn

At page 2 of the Office Action, the Examiner objected to the Title. Applicants respectfully traverse this objection.

The Title has been amended to recite "IL-B50 Antibody." As discussed above, support for the Title is found in the present application and in the '318 application.

Applicants respectfully request that this objection be reconsidered and withdrawn.

III. Information Disclosure Statements

Applicants thank the Examiner for confirming at page 2 of the Office Action that document AH (Maeurer *et al.*, *The Cytokine Handbook*, 3rd Ed., "Interleukin-7" (1998), Chapter 9: 229-269) has been considered.

Document AE (Friend *et al.*, "A Thymic Stromal Cell Line Supports *In Vitro* Development Of Surface IgM+ B Cells And Produces A Novel Growth Factor Affecting B and T Lineage Cells," *Experimental Hematology 22(3)* : 321-328 (1994) ("the Friend document")) was listed on the Form PTO/SB/08 filed July 18, 2003, but this document has not yet been considered. Filed herewith is an information disclosure statement, and the Friend document is listed, among other documents, on the accompanying Form PTO/SB/08. Also filed herewith is a copy of the Friend document. Applicants respectfully request that the Examiner indicate that the listed documents have been considered, by returning an Examiner-initialed copy of the Form PTO/SB/08 to the undersigned.

Document AB, EP 0 314 415 A2, was listed on the Form PTO/SB/08 filed July 18, 2003, but the Examiner did not initial this document on the Form PTO/SB/08. Applicants

respectfully request that the Examiner indicate that EP 0 314 415 A2 has been considered, by returning an Examiner-initialed copy of the Form PTO/SB/08 to the undersigned.

IV. The Written Description Rejection Should Be Withdrawn

Claims 21 and 28-40 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description. Applicants respectfully traverse this rejection.

Claims 28-40 have been canceled. With respect to the rejection of Claim 21, Applicants provide the following remarks.

A. Claims 21 and 28-40 Are Described In The Present Application And In The '318 Application, To Which The Present Application Claims Priority

Claim 21 has been amended to recite an isolated antibody or fragment thereof that specifically binds a polypeptide consisting of SEQ ID NO:2. As established above in Section I of this paper, the subject matter of claim 21 is described in the present application and in the '318 application.

B. The Alleged Basis For The Written Description Rejection Is Improper

Underlying the written description rejection is the allegation that, because the '318 application allegedly fails to disclose a utility for the claimed invention, the claimed invention does not have priority to the '318 application. According to the Examiner,

> [b]ecause the specific, substantial and credible utility of the instant polypeptide consisting [sic] SEQ ID NO: 2 is only disclosed in the specification of continuation application 09/963,347 filed on 09/25/2001, the effective filing date for the instant invention is determined as the filing date of continuation application 09/963,347 i.e. 09/25/2001."

Office Action at page 3.

Applicants respectfully disagree. Utility for the claimed invention is disclosed in the '318 application. A prima *facie case* of lack of utility has not been established. As a result, the claimed invention has priority to the '318 application

1. Utility For The Claimed Invention Is Disclosed In The '318 Application

a. The Disclosed Utility Is Specific

Because the threshold of utility is not high under 35 U.S.C. § 101, an invention is useful if it is merely capable of providing some identifiable benefit. *Juicy Whip, Inc. v.*

Orange Bang, Inc., 185 F.3d 1364, 1366 (Fed. Cir. 1999). In other words, only a minimal utility is required. Here, the disclosure in the '318 application is sufficient to meet the minimal utility standard set forth in 35 U.S.C. § 101.

At least one specific utility has been disclosed in the '318 application for the polypeptide of SEQ ID NO: 2, *i.e.*, IL-B50. For example, the '318 application discloses that IL-B50 is likely to have stimulatory or inhibitory effects on hematopoietic cells, including *e.g.*, lymphoid cells, such as T-cells, B-cells, natural killer cells, macrophages, dendritic cells, and hematopoietic progenitors. *See* the '318 application at page 9, lines 9-13. The '318 application also discloses that IL-B50 may also be useful in the treatment of immune disorders, *e.g.*, T cell immune deficiencies, chronic inflammation, or tissue rejection, or in cardiovascular or neurophysioloigcal conditions. *See* the' 318 application at page 13, lines 1-4.

The '318 application also discloses that IL-B50 and IL-7 are likely to share similar biological functions, (*see* page 12, lines 1-4), and that IL-7 exhibits strong effects on lymphopoietic development and differentiation (*see* page 59, lines 21-22). The '318 application also discloses that IL-B50 would bind to the alpha subunit of the IL-7 receptor along with another receptor subunit (*see* page 49, lines 25-28).

Evidence of structural similarity to a compound known to have a particular therapeutic or pharmacological utility is supportive of an assertion of therapeutic utility for a new compound. M.P.E.P. § 2107.03, part II. One of ordinary skill in the art would have understood from the '318 application that the polypeptide of SEQ ID NO: 2 has similar functions as IL-7, such as stimulating lymphopoietic development and differentiation. As a result, an antibody or fragment thereof that binds to the polypeptide of SEQ ID NO:2 would also have specific utility.

b. The Disclosed Utility Is Substantial

According to the M.P.E.P., "[c]ourts have repeatedly found that the mere *identification* of a pharmacological activity of a compound is relevant to an asserted pharmacological use provides an 'immediate benefit to the public' and satisfies the utility requirement." M.P.E.P. § 2107.01, part III.

Here, the identification of the polypeptide of SEQ ID NO: 2 as having an effect on hematopoietic cells and having a role in treating immune disorders provides researchers and physicians with a new target for intervention in immune disorders and disease. As a result, the claimed antibody or fragment thereof has a "real world" use. Therefore, the utility

disclosed in the '318 application for the polypeptide of SEQ ID NO: 2 and antibodies (and fragments thereof) that bind to the polypeptide of SEQ ID NO: 2 is substantial.

c. ***The Disclosed Utility Is Credible***

An assertion of utility is credible *unless* the logic underlying the assertion is